



DEPARTMENT OF THE AIR FORCE  
59TH MEDICAL WING (AETC)  
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

14 NOV 2016

MEMORANDUM FOR ST/SGVUS


ATTN: DR. ANNEKE C. BUSH

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **What to Consider for Animal Research** presented at **Resident Research Fundamentals Course (Gateway Club), JBSA- Lackland TX, 27 Oct 16** in accordance with MDWI 41-108, has been approved and assigned local file #**16382**.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.


LINDA STEEL-GOODWIN, Col, USAF, BSC  
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Anneke C. Bush, GS-14, 59 MDW/ST/SGVUS	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER:
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: What to Consider for Animal Research			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input checked="" type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting ) Resident Research Fundamentals Course (Gateway Club), JBSA-Lackland Tx, 27 Oct 16			
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE N/A			
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Lopez, Raquel, L., raquel.lopez.2.ctr@us.af.mil			14. DUTY PHONE/PAGER NUMBER 210-292-3366
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Anneke C. Bush	GS-14	59 MDW/ST/SGVUS	
b.			
c.			
d.			
e.			
f.			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
16. AUTHOR'S PRINTED NAME, RANK, GRADE Anneke C. Bush GS 14 DAF		17. AUTHOR'S SIGNATURE 	18. DATE 27 OCT 16
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE KEVIN STEEL, LTJG, 59MDW/STJ		20. APPROVING AUTHORITY'S SIGNATURE 	21. DATE 27 OCT 16



PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
<b>1st ENDORSEMENT (59 MDW/SGVU Use Only)</b>			
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.		22. DATE RECEIVED 11/1/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16382
24. DATE REVIEWED		25. DATE FORWARDED TO 502 ISG/JAC	
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. <input type="checkbox"/> N/A			
27. COMMENTS <input checked="" type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED			
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Linda D Harris, GS 14, Chief, Ops Br		Digitally signed by HARRIS LINDA DAWN 1131890580 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=HARRIS LINDA DAWN.1131890580 Date: 2016.11.08 09:38:19 -0600 HARRIS LINDA DAWN WN.1131890580	30. DATE 7 Nov 16
<b>2nd ENDORSEMENT (502 ISG/JAC Use Only)</b>			
31. DATE RECEIVED		32. DATE FORWARDED TO 59 MDW/PA	
33. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		35. REVIEWER SIGNATURE	36. DATE
<b>3rd ENDORSEMENT (59 MDW/PA Use Only)</b>			
37. DATE RECEIVED November 8, 2016		38. DATE FORWARDED TO 59 MDW/SGVU November 14, 2016	
39. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin linuma, SSgt/E-5, 59 MDW Public Affairs		Digitally signed by LINUMA KEVIN MITCHELL 1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=LINUMA KEVIN MITCHELL.1296227613 Date: 2016.11.14 08:34:18 -0600 LINUMA KEVIN MITCHELL SUGU.1296227613	42. DATE November 14, 2016
<b>4th ENDORSEMENT (59 MDW/SGVU Use Only)</b>			
43. DATE RECEIVED		44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE	
45. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED			
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		47. REVIEWER SIGNATURE	48. DATE

**59th Clinical Research Division**  
 Wilford Hall Ambulatory Surgical Center  
*Develop America's Medical Airmen Today ... for Tomorrow*




**27 Oct 2016**  
**Dr. Anneke C. Bush**  
*"In the Name of Humanity"*  
*Providing Great Care...Building Warrior Medics*

**Animal Use Program**  
*Develop America's Medical Airmen Today ... for Tomorrow*

- Facility/Vivarium/Staff

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**CRD Capabilities**  
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- Capabilities:
  - AAALACi Accredited Vivarium
  - 25K sq. ft. Facility
  - 31K sq. ft. Paddock
  - WHASC IACUC
  - AFMS IRB
  - 1 Radiology Suite
  - 3 Surgery Suites
  - DaVinci Robotic Trg Suite
  - State-of-the-Art Lab

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**Personnel**  
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- (1) DVM - DACLAM, MPH
- (1) DVM - Certified by American College of Veterinary Pathology - 7 years Veterinary Pathology experience
- (1) PhD, Aerospace Physiology (IRB Administrator)
- (1) ScD, MHS Statistical Consultant/Epidemiology (IACUC Administrator)
- (1) Registered Nurse Anesthesia Specialist
- (1) PhD Chemist
- (1) PhD Biochemist (Director, Research QA /QI)
- (1) PhD Biologist with emphasis in Neurology
- (8) MS Degree - 10-30 years research experience

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## Personnel



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- (1) Surgical Supervisor- 33 years of OR experience
- (1) Biological Animal Technician - 20+ years OR experience
- (1) Instron/Hyper/Hypobarics Technician - 20+ years of medical veterinary experience
- (1) Certified Laboratory Animal Technician (AALAS)
- (2) Certified/Registered Laboratory Animal Technologists (AALAS)
- (5) Certified Clinical Laboratory Technologist
- (3) Active Duty Surgical Techs (4N1)
- (5) Civilian Surgical Techs
- (4) Active Duty Medical Admin Techs; (6) Civilian Admin Techs

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## Accreditation/Assurances


### Animal Program




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- Association For Assessment And Accreditation of Laboratory Animal Care International (AAALAC) Accredited
  - Last Visit - 15 June 2016(Due Every 36 Months)
  - CRD hailed as a "A Best Practice Site"
  - "Emeritus Status" for 21 consecutive years (no major findings)
- PHS Assurance
  - Only Air Force Facility with OLAW (PHS) Assurance
  - Allows us to accept PHS funding for clinical investigations

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## Site Visits




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- Animal Research Protection Program Compliance SAV - Bi-Annual by AF Medical Support Agency/SGE-C
  - SAV Pending - TBD FY17
- AAALAC - triennial accreditation site visit
  - 15 June 2016

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## Animal Use Program



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- Facility/Vivarium/Staff
- IACUC - Institutional Animal Care & Use Committee

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### Subject Protection Program Responsibilities

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- Protection of Animal Research Subjects/IACUC
  - Set animal use policy
  - Review, modify, approve/disapprove all animal use protocols
  - Ensure training for all personnel working with animals

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### IACUC Requirements

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CATEGORY	USDA	PHS	Guide	Ag G	DoD
Veterinarian with program authority	✓	✓	✓	✓	✓
- qualified in agricultural animal medicine & veterinary medicine				✓	
Non-Affiliated	✓	✓	✓	✓	✓
Practicing Scientist		✓	✓	✓	
- w/expertise in agricultural research or teaching involving agricultural animals				✓	
- w/expertise in animal, dairy, or poultry & management of agricultural animals				✓	
Non-Scientist		✓		✓	✓
Minimum Number of members	3	5	3	3	5

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### Institutional Animal Care and Use Committee

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- IACUC must follow PHS Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act USDA Title 7, Ch 2131, 9 CFR parts 1-4
- DoDI 3216.01 Use of Laboratory Animals in DoD Programs
- Accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
- Reports directly to the Institutional Official (IO)
- Second Level Review at SG level

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### IACUC Responsibilities

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- Responsible for the Oversight and Evaluation of the Institution's Laboratory Animal Care and Use Program
  - Review the institution's program for Humane Care and Use of Animals
  - Inspect all the institution's animal facilities semi-annually
  - Submit reports of IACUC evaluations to the IO
  - Review concerns involving care and use of animals
  - Make recommendations to the IO regarding any aspect of the program
  - Review and approve, require modifications (to secure approval) or withhold approval of activities involving animals (research or training protocols)

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## IACUC Responsibilities (cont.)



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- Review and approve, require modifications (to secure approval) or withhold approval of proposed significant changes (protocol amendments)
- Suspend an activity involving animals
- Ensure personnel who use or care for animals are properly trained
- Ensure there is an adequate Occupational Health and Safety Program
- Bottom line: the IACUC is responsible for all aspects of the institution's animal care and use program

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## Animal Use Program



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- Facility/Vivarium/Staff
- IACUC – Institutional Animal Care & Use Committee
- Investigators

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## Animal Research Protocol Requirements



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- PIs and AIs must complete the Animal Care and Use courses located on the AALAS Learning Library prior to doing animal research
- PIs must consult the CRD veterinarian, Dr. Dawn Harris, for assistance in protocol development prior to submission to the IACUC
- Templates are available from the protocol office staff

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## Animal Research Protocol Requirements



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- Standard DoD Animal Use Protocol
  - May have facility specific language
- Cover sheet with Signatures
- Non-technical synopsis
- Literature reviews
  - Search for duplication of effort
  - Search for alternatives to painful procedures
- Study Hypothesis, design, statistical review
- Veterinary considerations including pain management and study endpoints
- Table of qualifications of investigators

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## Animal Research Protocol Life Cycle

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- IACUC Submission Deadlines
- Pre-review process
- IACUC review and approval
- Second level approval, if applicable
- Funding and scheduling
- Annual Reviews
- Triennial de novo review
- Final Report

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## 59th Clinical Research Division Website

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- Home
- Animal Research
- CRD Capabilities
- Calendar
- Funding
- Points of Contact
- Clinical Research
- News



59th Medical Wing  
Clinical Research Division

Calendar

CRD Capabilities

Clinical Research Division  
Points of Contact

Current Research

Human/Non-Human  
Research

Animal Research

News


<https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx>

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## Points of Contact

*Develop America's Medical Airmen Today ... for Tomorrow*




- Col Linda Steel-Goodwin, Division Chief & Institutional Official 292-7068
- Dr. L. Dawn Harris, DVM, MPH, DACLAM Laboratory Animal Medical Officer 292-2771
- Dr. Anneke Bush, ScD, MHS, IACUC Chair 292-7295
- Mrs. Maria Dominguez 292-6095
- Ms. Jessica Mercado 292-2977
- Ms. Rachel Montez 292-4683


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## Questions?

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59th CLINICAL RESEARCH DIVISION  
59th MEDICAL WING, JBSA LACKLAND, TEXAS

**"If we knew what it was we were doing, it would not be called research, would it?"**  
**- Albert Einstein**

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